


University of Medicine and Dentistry of New Jersey
Robert Wood Johnson Medical School at Camden

 The Cooper Health System

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November 10, 2000

Docket's Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1-23
12420 Parklawn Drive
Rockville MD 20857

Docket #: 00P-1499/CP1

To Whom It May Concern:

After reading the letter sent by Sidney Wolf dated October 30th and his group "Public Citizen" to the FDA I felt the need to respond as a practicing physician. After carefully reviewing the letter I feel that it contains a significant amount of material that is neither accurate nor reflects the views of the majority of practicing physicians. As a practicing gastroenterologist at a University Medical Center I have the opportunity to treat a large number of patients with Functional Bowel Disease. I have been using Lotronex regularly since it was FDA approved in the early spring and have found it to be a quite remarkable drug. I have a large number of patients on this drug currently and have not run into any serious side effects nor any significant adverse events.

Irritable Bowel Syndrome is a very serious disorder for a large number of patients in this country. While certainly many people have mild to moderate symptoms large groups of patients have serious limitations secondary to this chronic lifelong disease. Their symptoms frequently preclude them from living a "normal" life often making it difficult for them to travel, accept new jobs or even do simple things such as going shopping with friends or even out to restaurants. I have had a large number of remarkable success stories by using Lotronex. I have a number of patients who feel it has significantly changed their life. I certainly have received my share of phone calls over the last few weeks with questions regarding this medication but not a single patient who feel it has helped them has stopped taking it. As a matter of fact several who I have spoken to or seen in the office, expressed great concern about the publicity and were desperate to ensure that they would still be able to obtain this medication as it has made such a remarkable difference in their lives. As Irritable Bowel Syndrome is such a

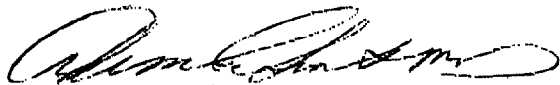
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prevalent disease affecting twenty percent of the population, I certainly hope the FDA is not even considering placing any limitations on access to this medication. I absolutely believe that Sidney Wolf's letter was based more on publicity seeking reasons than for actual concern for patient safety. If he had any idea as to the severity of this disease and its effect on patient's quality of life he would not had the temerity to write and publish such a letter. There is no doubt in my mind that this is a safe, beneficial medication when used properly and for the correct patient population. It would be quite unfortunate if the FDA allowed publicity seeking organizations like Public Citizen to influence the availability and appropriate use of a medication that has made such a difference in many patient's lives.

Sincerely,



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